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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,491	02/13/2001	Dallas L. Clouatre		8229

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	16

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,491	CLOUATRE ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-18 are pending.

2. Claims 1-18 are rejected.

Response to Arguments

3. Applicants' arguments filed January 28, 2003 have been fully considered but they are not persuasive with respect to Shrivastava et al. Applicants make the following arguments. Applicants first allege that Shrivastava et al. do not render the instant invention obvious. Applicants also discuss various prior art teachings, namely the reference of Lowenstein, that were not applied in a previous rejection. Next, applicants argue that Shrivastava et al. do not test anti-hypertensive properties of magnesium (-) hydroxycitrate.

4. First, applicants allege that Shrivastava et al. do not render the instant invention obvious. It is important to note that not only does Shrivastava et al. render the instant invention obvious but also Shrivastava et al. anticipate the instantly claimed invention, (see paragraphs 4 and 5 of the Office Action dated November 25, 2002), which was not addressed in applicants' arguments of January 28, 2003. Shrivastava et al. teach of a magnesium (-) hydroxycitrate composition that "has been found to be endowed with antihypertensive properties.", (see column 2, lines 35, 36 and 46-48).
Applicants also discuss various prior art teachings, namely Lowenstein. This reference was not used in a rejection so it will not be discussed in this response to applicant

arguments section. What will be discussed; is the fact that the skilled artisan is specifically taught that a salt of (-) hydroxycitrate, such as magnesium (-) hydroxycitrate, is used to treat hypertension. The Office action of November 25, 2002 states that it is well within the level of one having ordinary skill in the art, especially after using the teachings of Shrivastava et al., to substitute or replace one pharmaceutically acceptable cation for another. Accordingly, it the magnesium salt of (-) hydroxycitrate possesses very useful pharmacological properties, inter alia, antihypertensive properties, then the skilled artisan would have been motivated to replace one pharmaceutically acceptable cation for another pharmaceutically acceptable cation, such as sodium or potassium or calcium. In addition, applicants recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

5. The prior art reference of Shrivastava et al. specifically discloses that magnesium (-) hydroxycitrate has antihypertensive properties. In addition, Shrivastava et al. disclose that magnesium (-) hydroxycitrate is, "also used in both curative and the preventable treatment of arterial hypertension", (see column 2, lines 62 and 63). Shrivastava et al. also teach that magnesium (-) hydroxycitrate is prepared in a "medicament intended for the treatment of a cardiovascular disease, in particular intended for the treatment of a localized or generalized pathology caused by cholesterol or of hypertension", (see column 4, lines 61 and 62 as well as column 5, lines 1-4). Shrivastava et al. further teach under the "particularly preferred conditions" magnesium

(-) hydroxycitrate is used "for the treatment of arterial hypertension", (see column 5, lines 9-12).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shrivastava et al. of U.S. Patent No. 6,221,901 B1 possessing a 102(e) date of April 22, 1999. Shrivastava et al. teach of the therapeutic administration of(-) hydroxycitrate to treat a variety of ailments including hypertension, (see column 2, lines 34-48). Shrivastava et al. establish the interchangeability between (-) hydroxycitrate and (-) hydroxycitric acid.

8. The rejection of claims 1 and 4-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Littera et al. of EP 803,202 A2, possessing a publication date of October 29, 1997 is withdrawn.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shrivastava et al. of U.S. Patent No. 6,221,901 B1 in view of Solomons and McMurry. Shrivastava et al. establish the interchangeability between (-) hydroxycitrate

and (-) hydroxycitric acid. Moreover, it is well within the level of the skilled artisan to convert between acid and its conjugate base, for instance (-) hydroxycitric acid and (-) hydroxycitrate. Shrivastava et al. teach of the therapeutic administration of (-) hydroxycitrate to treat a variety of ailments including hypertension, (see column 2, lines 34-48). Shrivastava et al. also teach that it is well known in the art that a composition containing (-) hydroxycitrate is used to combat excess weight and obesity, (see column 1, lines 27-30). Shrivastava et al. is silent to the lactone form of the (-) hydroxycitrate, it is widely accepted in the art that the cyclization of 5-membered ring into a lactone from its acyclic acid chain occurs readily. In fact, carboxylic acids whose molecules have a hydroxyl group on a gamma- or delta- carbon atom undergo an intramolecular esterification to give cyclic esters known as gamma- or delta- lactones, (see page 799 of Solomons, Organic Chemistry 3rd Edition). It is also known in the art that carboxylic acid can be readily converted into other carboxylic acid derivates, such as carboxylic acid esters and amides, (see McMurry of Organic Chemistry, 2nd Edition, pages 759-767). It is also within the purview of the skilled artisan to simply convert an acidic group of an active agent, for instance (-) hydroxycitrate, into its corresponding ester and/or amide derivatives for the purpose of generating controlled-release forms of the active agent because these derivatives have the extra step of either removing the ester or amide groups before the active agent can be utilized. Although the prior art reference of Shrivastava et al. teaches of using the magnesium salt of hydroxycitrate it is well within the level of skill of the artisan to substitute one pharmaceutically acceptable cation for another. The determination of a dosage having the optimum therapeutic index, which

includes pharmaceutically acceptable salts, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Accordingly, the reference makes obvious the instant invention.

13. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shrivastava et al. of U.S. Patent No. 6,221,901 B1 in view of Solomons and McMurry and in further view of DiPiro et al. Shrivastava et al. establish the interchangeability between (-) hydroxycitrate and (-) hydroxycitric acid. Moreover, it is well within the level of the skilled artisan to convert between acid and its conjugate base, for instance (-) hydroxycitric acid and (-) hydroxycitrate. Shrivastava et al. teach of the therapeutic administration of (-) hydroxycitrate to treat a variety of ailments including hypertension, (see column 2, lines 34-48). Shrivastava et al. also teach that it is well known in the art that a composition containing (-) hydroxycitrate is used to combat excess weight and obesity, (see column 1, lines 27-30). Shrivastava et al. is silent to the lactone form of the (-) hydroxycitrate, it is widely accepted in the art that the cyclization of 5-membered ring into a lactone from its acyclic acid chain occurs readily. In fact, carboxylic acids whose molecules have a hydroxyl group on a gamma- or delta- carbon atom undergo an intramolecular esterification to give cyclic esters known as gamma- or delta-lactones, (see page 799 of Solomons, Organic Chemistry 3rd Edition). It is also known in the art that carboxylic acid can be readily converted into other carboxylic acid derivates, such as carboxylic acid esters and amides, (see McMurry of Organic Chemistry, 2nd Edition, pages 759-767). It is also within the purview of the skilled

artisan to simply convert an acidic group of an active agent, for instance (-) hydroxycitrate, into its corresponding ester and/or amide derivatives for the purpose of generating controlled-release forms of the active agent because these derivatives have the extra step of either removing the ester or amide groups before the active agent can be utilized. Although the prior art reference of Shrivastava et al. teaches of using the magnesium salt of hydroxycitrate it is well within the level of skill of the artisan to substitute one pharmaceutically acceptable cation for another. The determination of a dosage having the optimum therapeutic index, which includes pharmaceutically acceptable salts, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Accordingly, the reference makes obvious the instant invention.

14. DiPiro et al. teach that body weight and obesity are common characteristics in diabetes. DiPiro et al. also teach of various causes of diabetes, inter alia, elevated insulin and glucocorticoids and hormones, (see Table 54.1 on page 806 and pages 805-811). Accordingly, by treating hypertension as well as obesity with the administration of (-) hydroxycitrate or an analog thereof to an individual in need thereof, the individual would also be treating diabetes by inter alia, controlling the weight of the individual and also by lowering glucose levels as well as insulin and other hormones, see DiPiro et al. Clearly, it would have been obvious to the skilled artisan that by treating an individual with (-) hydroxycitrate, glucose, insulin and other hormone levels could be modified and manipulated especially since it is known in the art that obesity is related to diabetes and that a composition containing (-) hydroxycitrate is known to treat obesity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
June 5, 2003.